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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,284	02/07/2005	Gesine Schliecker	I-2002.001 US	5686

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EXAMINER	
PERREIRA, MELISSA JEAN	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,284	SCHLIECKER ET AL.	
	Examiner	Art Unit	
	MELISSA PERREIRA	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19 and 21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/9/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-19 and 21 are pending in the application. Claim 20 was canceled in the amendment filed 3/26/08. Any objections and/or rejections from previous office actions that have not been reiterated in this office action are obviated.

New Grounds of Rejection

Response to Arguments

1. Applicant's arguments with respect to claims 1-19 and 21 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Krone et al. (US 5,391,696) in view of Suzuki et al. (US 6,015,789) and in further view Ishino et al. (*Chem. Pharm. Bull.* **1992**, *40*, 3036-3041) and Maggi et al. (*Biomaterials* **2002**, *23*, 1113-1119).

4. Krone et al. (US 5,391,696) teaches of a controlled release formulation (abstract) containing polytartrate polymer, such as (2',3'-(1',4'-diethyl)-L-tartyl poly-(2,3-O-isopropylidene)-L-tartrate), buserelin and pharmaceutically acceptable excipients (example 11; column 10, lines 57-58). The controlled release formulations may

comprise a mixed polytartrate-PEG polymer and other physiologically accepted auxiliaries (column 10, lines 36-45). Krone et al. does not disclose the process for the preparation of a polytartrate tablet or the GnRH agonist nafarelin.

5. Suzuki et al. (US 6,015,789) discloses a controlled release pharmaceutical composition/tablet containing a GnRH agonist, such as buserelin or nafarelin, pharmacologically acceptable carrier, etc. for administration to a human being (column 97, lines 63-66; claim 2; column 98, lines 17-20).

6. Ishino et al. (*Chem. Pharm. Bull.* **1992**, *40*, 3036-3041) discloses pulsatile release tablet systems with a PEG shell where thickness and PEG content controlled T_p and rate constant (p3036, paragraph 4; p3038, paragraph 3). The granulation method for preparation of tablets involves mixing the ingredients in powder form, pulverizing and passing granules through a sieve (p3037, granulation).

7. Maggi et al. (*Biomaterials* **2002**, *23*, 1113-1119) discloses controlled release PEO tablets prepared via direct compression at compression forces of 10 and 30 kN (p1114, column 2, paragraph 2). The compression force seems to have no influence on the dissolution behavior of the matrices (p1115, column 2, paragraph 4) but the molecular weight of the polymer influenced the swelling behavior of the tablet and the overall release process (p1117, last paragraph; p1119, conclusion). 44

8. It is respectfully pointed out that instant claims 1-11 and 13 are product-by-process limitations. Claim 1 recites, "tablet prepared with a tablet press using a compression force of from 10 to 65 kN/cm^{2}" which is a product-by-process limitation as the instant claim is drawn to a pharmaceutical composition and not to a method of

making. The instant claims 2-11 and 13 depend on claim 1. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

9. At the time of the invention it would have been obvious to one ordinarily skilled in the art that the PEG containing controlled release tablet/formulation of Krone et al. may be pulsatile as Ishino et al. discloses a PEG containing pulsatile tablet formulation. One skilled in the art would have a reasonable expectation of success for substituting one equivalent GnRH agonist for another, such as buserelin for nafarelin. It is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect. The preparation and the compression of a PEG containing tablet at 10 or 30 kN are known in the art for controlled release formulations/pulsatile delivery systems and therefore it would be predictable to utilize these compression forces for the preparation of the PEG containing pulsatile tablet formulations of the combined disclosures above (comprising buserelin of nafarelin).

Conclusion

10. No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618